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AF/1647

Docket No.: PF-0526 USN

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By: _____ Printed: Katherine Stofer

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	Tang et al.		
Title:	HUMAN TRANSMEMBRANE PROTEINS		
Serial No.:	09/700,590	Filing Date:	April 16, 2001
Examiner:	Seharaseyon, J.	Group Art Unit:	1647

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

TRANSMITTAL FEE SHEET

Sir:

Transmitted herewith are the following for the above-identified application:

1. Return Receipt Postcard; and
2. Petition to Withdraw Holding of Lack of Unity of Invention (4 pp.).

The fee has been calculated as shown below.

X No additional Fee is required.

The Commissioner is hereby authorized to charge any additional fees required under 37 CFR §§ 1.16 and 1.17, or credit overpayment to Deposit Account No. 09-0108. **A duplicate copy of this sheet is enclosed.**

Respectfully submitted,

INCYTE CORPORATION

Date: March 25, 2004

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PETITION TO WITHDRAW HOLDING OF LACK OF UNITY OF INVENTION

Sir:

This is a petition under 37 C.F.R. § 1.144 requesting withdrawal of the holding of lack of unity of invention in the above identified application. In particular, Applicants request withdrawal of the holding of lack of unity of invention between claims drawn to polynucleotides and claims drawn to the polypeptides encoded by the polynucleotides. At the very least, the unity of invention standard requires that claims drawn to polypeptides of SEQ ID NO:22 be examined together with the claims currently under consideration, drawn to polynucleotides encoding SEQ ID NO:22 (including polynucleotides of SEQ ID NO:101).

The Office Action of March 25, 2003 maintained the restriction requirement between Group I (Claims 21, 22, 35, and 36) directed to polypeptides of SEQ ID NO:22) and Group II (Claims 23-29 and 31 directed to polynucleotides encoding the polypeptide of SEQ ID NO:22, including SEQ ID NO:101). The Examiner asserted that there is a lack of unity of invention between the recited polypeptides and polynucleotides.

The Office Action mailed March 25, 2003 stated that the DNA and protein may be searched and examined together if the claim set is drafted as in the format of Example 17, Part 2 of Annex B to the Administrative Regulations Under the PCT, and if the DNA and protein are both free over the prior art. The Office Action stated that SEQ ID NO:1 was not free over the prior art, as reference polynucleotides AA779652 and AA447814 had identity over portions of polynucleotides encoding SEQ ID NO:1. Applicants respectfully note that the claims, as amended in the Response to Office Action filed June 24, 2003 are directed to SEQ ID NO:22/101, not to SEQ ID NO:1 or polynucleotides encoding it. No evidence has been presented that either SEQ ID NO:22 or SEQ ID NO:101 are not free of the prior art. Thus Applicants believe that unity of invention should be applied since the claims are novel and unobvious over the cited art, and are linked by a special technical feature (the sequence of SEQ ID NO:22, encoded by SEQ ID NO:101) to form a single inventive concept. Thus the protein as well as the nucleotide claims should be examined together in this application.

Applicants further note that the decision in the Office Action mailed March 25, 2003, contradicts accepted practice under the unity of invention standard.

The instant application is a national stage application under 35 U.S.C. § 371 of international patent application PCT/US99/11904. The unity of invention standard must be applied in national stage applications. Section 1850 of the Manual of Patent Examining Procedure (February 2003 revision of the original 8th edition) (hereinafter "M.P.E.P.") provides:

> . . [W]hen the Office considers international applications . . . during the national stage as a Designated or Elected Office under 35 U.S.C. § 371, PCT Rule 13.1 and 13.2 will be followed when considering unity of invention of claims of different categories without regard to the practice in national applications filed under 35 U.S.C. 111. . .
>
> In applying PCT Rule 13.2 to . . . national stage applications under 35 U.S.C. 371, examiners should consider for unity of invention all the claims to different categories of invention in the application and permit retention in the same application for searching and/or preliminary examination, claims to the categories which meet the requirements of PCT Rule 13.2.

M.P.E.P. section 1893.03(d) reiterates the Patent Office's obligation to apply the Unity of Invention standard PCT Rule 13.2 instead of U.S. restriction/election of species practice:

> Examiners are reminded that unity of invention (not restriction) practice is applicable. . . in national stage applications submitted under 35 U.S.C. 371.

Therefore, the unity of invention standard must be applied to the instant application.

Specific provisions of the Administrative Regulations Under the PCT and the corresponding provisions of the M.P.E.P. strongly support a finding of unity of invention among claims to polynucleotides and claims to the polypeptides encoded by the polynucleotides. Example 17, Part 2 of Annex B to the Administrative Regulations Under the PCT provides that unity of invention is accepted as between claims to polypeptides and claims to polynucleotides encoding those polypeptides:

> Claim 1: Protein X
>
> Claim 2: DNA sequence encoding protein X.
>
> Expression of the DNA sequence in a host cell results in the production of a protein which is determined by the DNA sequence. **The protein and the DNA sequence exhibit corresponding special technical features. Unity of invention between claims 1 and 2 is accepted.** [emphasis added]

This Example is explicitly cited in M.P.E.P. section 1893.03(d) ("[n]ote also examples 1-17 of Annex B Part 2 of the PCT Administrative Instructions . . .").

Thus, in the present case, unity of invention exists as between claims drawn to polypeptides of the invention (e.g., Claims 21, 22, 35, and 36) and claims drawn to polynucleotides which encode those polypeptides (e.g., Claims 23-29 and 31). At the very least, unity of invention exists between claims drawn to polypeptides of SEQ ID NO:22 and claims drawn to the polynucleotides encoding the polypeptides of SEQ ID NO:22 (e.g., polynucleotides of SEQ ID NO:101).

Therefore, Applicants respectfully request, at the very least, withdrawal of the holding of lack of unity of invention between claims drawn to polypeptides of SEQ ID NO:22 and claims drawn to polynucleotides encoding polypeptides of SEQ ID NO:22 (e.g., polynucleotides of SEQ ID NO:101). Applicants submit that claims drawn to polypeptides of the invention (e.g., Claims 21, 22, 35, and 36), as they relate to SEQ ID NO:22, should be searched and examined along with claims drawn to the polynucleotides encoding these polypeptides.

The holding of lack of unity of invention was made final in the Office Action of March 25, 2003 (Office Action, page 3). Consideration of a petition under 37 C.F.R. § 1.144 requires that reconsideration of the finding of lack of unity of invention (or requirement for restriction) must have been previously requested (see 37 C.F.R. § 1.144 and 1.181). Such reconsideration was requested in the Response to Restriction Requirement mailed on December 16, 2002.

Applicants believe that no fee is due with this communication. However, if the USPTO determines that a fee is due, the Commissioner is hereby authorized to charge Deposit Account No. **09-0108.**

Respectfully submitted,

INCYTE CORPORATION

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